

Attorney Docket No.: P-9858-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Goldberg, Michael Examiner: Not Yet Known
Serial No.: 10/500,822 Group Art Unit: 1654
Filed: July 7, 2004 Confirmation No.: 8526
Title: ORAL INSULIN THERAPY

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☒ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

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FILED: July 7, 2004
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The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge

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Page 3

of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

III) ☒ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

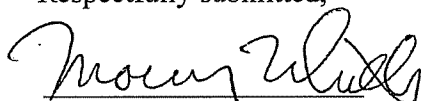
2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

3. ☒ The references being submitted herewith were submitted in an Information Disclosure Statement in this application on July 11, 2007, except that the Table of References (PTO/SB/08a) was inadvertently not submitted therewith. Pursuant to a teleconference with Examiner Christina Bradley on June 17, 2008, the Information Disclosure Statement that was submitted on July 11, 2007 is being resubmitted for consideration at this time along with the table of references and without requirement for the statement and fee required by 37 C.F.R §1.97(d).

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Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,



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Attorney/Agent for Applicant(s)
Registration No. 36,968

Dated: June 18, 2008

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PTO/SB/08a (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known		
				Application Number	10/500,822	
				Filing Date	July 7, 2004	
				First Named Inventor	Goldberg, Michael	
				Art Unit	1654	
				Examiner Name	Not Yet Known	
Sheet	1	of	2	Attorney Docket Number		P-9858-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A	US-5,968,515 B1	12-16-1997	PLATE et al	
	B	US-2002/0147135 A1	10-10-2002	SCHNELL	
	C	US-6,610,649 B2	08-26-2003	WAHREN et al	
	D	US-7,137,951	11-21-2006	PILARSKI	
	E	US-7,118,762	10-10-2006	BYRD	
	F	US-7,115,663	10-03-2006	MOYE-SHERMAN et al	
	G	US-7,084,114	08-01-2006	EKWURIBE et al	
	H	US-7,060,675	06-13-2006	EKWURIBE et al	
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
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Examiner Signature	/Christina Bradley/ (06/20/2008)	Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known	
				Application Number	10/500,822
				Filing Date	July 7, 2004
				First Named Inventor	Goldberg, Michael
				Art Unit	1654
(use as many sheets as necessary)				Examiner Name	Not Yet Known
Sheet	2	of	2	Attorney Docket Number	P-9858-US1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	I	Miller J. L., "Bedtime Insulin Added to Daytime Sulfonylureas Improves Glycemic Control in Uncontrolled Type II Diabetes", Clinical Pharmacology and Therapeutics, Vol. 53, No. 3., pp. 380-4, March 1993.	<input type="checkbox"/>
	J	Mesiha Mounir S., "Oral Absorption of Insulin Encapsulated in Artificial Chyles of Bile Salt, Palmitic Acid and α -Tocopherol Dispersions", International Journal of Pharmaceutics, Vol. 249, No. 1-2, pp. 1-5, 2002.	<input type="checkbox"/>
	K	Hosny Ehab A., "Oral Delivery of Insulin from Enteric-coated Capsules Containing Sodium Salicylate: Effect on Relative Hypoglycemia of Diabetic Beagle Dogs", International Journal of Pharmaceutics, Vol. 237, No. 1-2, pp. 71-76, 2002.	<input type="checkbox"/>
	L	Yki-Jarvinen H., "Comparison of Bedtime Insulin Regimens in Patients with Type II Diabetes Mellitus. A randomized, controlled trial.", Annals of Internal Medicine, Vol. 130, No. 5, pp. 389-96, March 2, 1999.	<input type="checkbox"/>
	M	Clement Stephen, "Oral Insulin Product Hexyl-Insulin Monoconjugate 2 (HIM2) in Type 1 Diabetes Mellitus: The Glucose Stabilization Effects of HIM2", Diabetes Technology & Therapeutics, V. 4, No. 4, pp. 459-66, August 2002.	<input type="checkbox"/>
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Examiner Signature	/Christina Bradley/ (06/20/2008)	Date Considered	
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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